

What is claimed:

1. A method for extracting, isolating, or concentrating an apoptotic body present in a bodily fluid, the method comprising the steps of:
 - a) contacting a bodily fluid with a primer or probe specific for a protein,
5 phospholipid, or nucleic acid present in an apoptotic body;
 - b) conjugating or hybridizing the primer or probe to the protein, phospholipid, or nucleic acid of the apoptotic body; and
 - c) separating the primer or probe from the bodily fluid, whereby the apoptotic body is thereupon extracted, isolated, or concentrated.
- 10 2. The method of claim 1 wherein the primer or probe is an antibody, or an oligonucleotide.
3. The method of claim 1 wherein the primer or probe is detectably labeled.
4. The method of claim 1 wherein the bodily fluid is blood, plasma, serum, urine, effusion, ascites, saliva, cerebrospinal fluid, cervical secretions,
15 amniotic fluid, gastrointestinal fluid or secretions, cystic fluid, sputum or bronchial secretions, or breast fluid.
5. A method according to claim 1, further comprising the step of:
 - d) extracting nucleic acid from the apoptotic body, and amplifying or
signal amplifying said nucleic acid or cDNA derived therefrom in a
20 qualitative or quantitative fashion.
6. The method of claim 3 wherein the labeled probe is labeled annexin V.
7. A method of detecting an apoptotic body present in a bodily fluid, the method comprising the steps of labeling the apoptotic body using a labeled primer or probe specific to a protein, phospholipid, or nucleic acid of the apoptotic
25 body, and detecting the labeled apoptotic body thereby.

8. The method of claim 7 wherein the primer or probe is conjugated with a label that is a fluorescent, radioisotope, biotin, or chromophore moiety and the primer or probe is detected thereby.
9. The method of claim 7 wherein the labeled probe is labeled annexin V.
- 5 10. A method of detecting an apoptotic body protein, phospholipid, or nucleic acid present in a bodily fluid, the method comprising the steps of:
- a) extracting, separating, isolating, or purifying an apoptotic body from the bodily fluid;
 - b) labeling the apoptotic body protein, phospholipid, or nucleic acid or its
10 amplified product using a labeled primer or probe specific for a protein, phospholipid, or nucleic acid of the apoptotic body; and
 - c) detecting the labeled apoptotic body protein, phospholipid or nucleic acid thereby.
11. The method of claim 10 wherein the primer or probe is conjugated with a
15 label that is a fluorescent, radioisotope, biotin, or chromophore moiety and the primer or probe is detected thereby.
12. The method of claim 10, wherein the apoptotic body in step (a) is disrupted by mechanical, ultrasound, microwave, or chemical means prior to labeling in step (b).
- 20 13. The method of claim 10, wherein the nucleic acid is extracted from the apoptotic body prior to labeling.
14. The method of claim 10, wherein the nucleic acid is extracted from the apoptotic body and amplified, or cDNA prepared therefrom is amplified, qualitatively or quantitatively prior to labeling and detection of the amplified
25 product.

15. A method according to claim 10, wherein the nucleic acid is extracted from the apoptotic body and hybridized.
16. A method according to claim 1, wherein the primer or probe is attached to a solid substrate.
- 5 17. The method of claim 16, wherein the solid substrate is a bead or particle.
18. A method according to claim 10, wherein the primer or probe is attached to a solid substrate.
19. The method of claim 18, wherein the solid substrate is a bead or particle.
20. The method of claim 18, wherein the solid substrate is a bioelectric interface.
- 10 21. A method for separating apoptotic bodies from cellular components of a bodily fluid, the method comprising the step of passing the bodily fluid through a filter having a pore size that permits passage of the apoptotic body through the filter and prevents passage of the apoptotic body through the filter.
- 15 22. A method for separating apoptotic bodies from cellular components of a bodily fluid, the method comprising the step of subjecting the bodily fluid to centrifugation at a speed and centrifugal force that separates the apoptotic bodies from cells or other particulate matter in the bodily fluid that are larger or denser than the apoptotic bodies.
- 20 23. A method according to claim 10, wherein detection of a labeled product is performed by gel electrophoresis, capillary electrophoresis, enzyme-linked immunosorbent assay, fluorescent-labeled probe, radioisotope-labeled probe, chromogenically-labeled probe, laser-induced fluorescence detection, Western blot analysis, Northern blot analysis, Southern blot analysis,
25 electrochemiluminescence, reverse dot blot detection, high-performance chromatography, spectroscopy, mass spectrometry, magnetic resonance

spectrometry, flow cytometry, laser scanning cytometry, or detection at a bioelectrical interface.

24. The method of claim 1, wherein presence of the apoptotic body in the bodily fluid is associated with a cancer or a premalignant condition.
- 5 25. The method of claim 10, wherein presence of the apoptotic body in the bodily fluid is associated with a cancer or a premalignant condition.
26. The method of claim 1, wherein the bodily fluid is obtained from a human with cancer.
27. The method of claim 10, wherein the bodily fluid is obtained from a human
10 with cancer.
28. The method of claim 1, wherein the bodily fluid is obtained from a human with a non-neoplastic disease.
29. The method of claim 24 further comprising the step of diagnosing, evaluating or monitoring the cancer or premalignant condition.
- 15 30. The method of claim 25 further comprising the step of diagnosing, evaluating or monitoring the cancer or premalignant condition.
31. A kit for extracting, separating, purifying, isolating, or concentrating apoptotic bodies from bodily fluid, said kit comprising one or a plurality of probes, primers, or antibodies attached to a solid substrate, wherein said
20 probes, primers, or antibodies are specific for phospholipid, protein, or nucleic acid associated with apoptotic bodies.
32. The method of claim 31, wherein the probe or antibody is specific for phosphatidylserine.
33. The method of claim 32, where in the probe or antibody is detectably-labeled
25 annexin V.

34. The method of claim 31, wherein the solid substrate is a solid surface, a bead or a particle.
35. A kit for extracting, separating, purifying, isolating, or concentrating apoptotic bodies from bodily fluid, said kit comprising, said kit comprising
5 one or a plurality of filters having a pore size between 6 micron and 0.1 micron.
36. A method of labeling an apoptotic body present in a bodily fluid, the method comprising the step of providing to the bodily fluid a labeling probe or primer moiety specific for a phospholipid, protein, or nucleic acid associated with the apoptotic
10 body.